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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/720,639	05/16/2001	Nissim Darvish	20066.73	3851

54042 7590 07/06/2006

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EXAMINER	
EVANISKO, GEORGE ROBERT	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 07/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/720,639	DARVISH ET AL.	
	Examiner	Art Unit	
	George R. Evanisko	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 April 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6, 7, 10-13,55, 56, 59-62,151,155,161,164,166,168,172,173 and 175-177* is/are pending in the application.

4a) Of the above claim(s) *152-154, 156-160, 165, 169-171* is/are withdrawn from consideration.

5)☒ Claim(s) *6,7,55 and 56* is/are allowed.

6)☒ Claim(s) *10-13,59-62,151,155,161,164,166,168,172,173 and 175-177* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *4/19/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 4/19/06 has been entered.

Election/Restrictions

Claims 152-154, 156-160, 165, and 169-171 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to non-elected embodiments, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 12/13/04.

Information Disclosure Statement

The information disclosure statement filed 4/19/06 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because several references are not complete or do not have an English translation or do not have a date. It has been placed in the application file, but the information referred to therein for thee lined through references has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10-15, 59-64, 151, 155, 161-164, 166-168, 172-177, 205 and 206 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter which was not disclosed is the extended pacing signal having an overall duration "within a single heartbeat". The original specification did not disclose the terminology of "within a single heartbeat". In addition, this is considered a new time limitation/range that precludes the use of other periods and was not set out in the original disclosure. Finally, the range or heart rate of "within a single heartbeat" is not set forth.

According to MPEP 2173.05(i), any negative limitation or exclusionary proviso must have basis in the original disclosure. The mere absence of a positive recitation is not basis for an exclusion. Any claim containing a negative limitation which does not have basis in the original disclosure should be rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 10-13, 59-62, 151, 155, 161, 164, 166, 168, 172, 173, and 175-177 are rejected under 35 U.S.C. 102(e) as being anticipated by Kroll et al (5978703).

Kroll applies a signal that is capable of meeting the intended use recitations of pacing the heart and inherently performs a method for pacing (claim 50), modifying a characteristic of pulsatile blood flow (claim 151), and increasing a contractility by 10% (claim 155), because he provides a signal (10-200 Volts [column 5, lines 10-19], 1-5 ms pulse width [figure 4], in a train of 10 pulses with 500 ms between pulses [figure 4, column 4, and/or column 5, line 59]) that will/can cause an action potential of the heart, therefore the signal will "pace" the heart. It is noted that the "overall duration" of the pulse train is greater than 8 ms since 10 pulses at 5 ms is equal to 50 ms or that the train has the claimed "period" of approximately 1 second since the dead time is included in the period. Also, Kroll discloses the use of sensors, 44 or 46, 406, for determining when to apply/modify the signal for the heart for enhancement, such as during arrhythmias (column 5, line 63 and column 6, lines 10-19). In addition, since his signal and electrodes will be used for increasing pulsatile/blood flow, they will inherently engender a redistribution of cardiac muscle mass. It is noted that applying pulses with a 500 ms interval will provide 1-2 pulses within a single heartbeat for a person with a heart rate of approximately 120 bpm and 2-3 pulses within a single heartbeat for a person with a heart rate of approximately 60 bpm.

Claims 10, 12, 13, 15, 59, 61, 62, 64, 151, 155, 164, 165, 166, 167, 172, 173, and 177 are rejected under 35 U.S.C. 102(b) as being anticipated by Freeman (5205284). Freeman shows the train of pulses in figure 3 having a duration of 20 msec to 150 msec (column 3, lines 20-27) and with a duty cycle of approximately 20-66% (column 4, lines 1-3). If the duty cycle is approximately 50%, the on time pulse duration will be half of the 20-150 msec pulse train, equaling approximately 10-75 msec of on time. In addition, Freeman inherently performs a method for modifying a characteristic of pulsatile blood flow (claim 151), and increasing a contractility by 10% (claim 155), because he provides a similar extended duration pacing signal as the applicant provides. Finally, Freeman modifies and determines when to deliver the pulses with his sensing system, 12 and delivers lower energy pulses in between the extended duration pacing pulses (claim 167) since the system can operate asynchronously and delivers the other pulses, 90.

Claims 205 and 206 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Mehra (5018522).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 10, 12-15, 59, 61-64, 151, 155, 161, 162, 164, 166, 168, 172, 173, 177, 205, and 206 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mower (6141586).

Mower applies a signal that is used for pacing the heart and performs a method for pacing, and inherently modifies a characteristic of pulsatile blood flow (claim 151), and increases a contractility by 10% (claim 155), because he provides a signal (8 ms anodal and 0.3-1.5 ms cathodal [column 5, lines 10-19 and column 8] or over 200 ms post heartbeat [column 5, line 5 and throughout] and 20 Volts) that will cause an action potential of the heart and is of the same or similar pulse duration and characteristic as the applicant's pulse. Also, Mower discloses the use of sensors, column 7, lines 20-35, for determining when to apply/modify the signal for the heart for enhancement. In addition, since his signal and electrodes will be used for increasing cardiac contraction and pulsatile/blood flow, they will inherently engender a redistribution of cardiac muscle mass. For claim 162, the signals will be applied "according to a predetermined time sequence" since the signals were programmed to be delivered "cyclically paced either on the same or similar time protocol or independently" (column 7, line 67). In addition, Mower calls his signal (including the anodal portion) a pacing or stimulation signal and therefore provides a pacing signal greater than 8 ms from a time of initiation of application of the signal that initiates action potential propagation. Although Mower says that the anodal portion could be

subthreshold, this occurs in an "alternative embodiment" (column 8, line 41). Finally, for claims 205 and 206, it is noted that the biphasic signal of figures 4-6 is a single pulse (one pulse with two phases). In addition, even if the alternative embodiment pulse of the first part of the pulse is subthreshold, the second part of the pulse does cause an action potential. Since any pulse delivered to a cell changes its action potential threshold, this will be the beginning/initiation of that portion of the signal that initiates action potential propagation. This is similar to what the applicant argues in the paper of 4/19/06 and what is described in the applicants specification on page 17. If the overall duration of the pulse is greater than 8 ms, the first 1-2 ms of the pulse is what initiates the action potential, i.e. it is subthreshold since no action potential has resulted yet, which is similar to Mowers alternative embodiment subthreshold first phase of the pulse.

Claim 167 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Kroll et al. Kroll states that he uses his system in a pacemaker, shows in column 5 that pacemakers use lower energy pulses than his extended signals, and only provides his extended signal for responsive to a demand for enhancement and therefore will apply the pacing signal in the absence of the demand.

In the alternative, Kroll discloses the claimed invention except for applying a lower energy pacing signal in the absence of the enhancement signal. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method using the extended signal pacemaker as taught by Kroll, with a pacing signal in the absence of the enhancement signal since it was known in the art that pacemakers apply a low energy pacing signal (lower than the energy of Kroll's extended signal) and in the absence of an enhancement

signal related to pressure or fibrillation, asystole, tachycardia, etc to provide a low energy signal that can pace the heart over a longer period for bradycardia.

Claims 163 and 167 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Mower. Mower teaches the use of his ventricular extended pacing signal in an atrial pacemaker (column 9) and inherently will be of a smaller duration and lower energy and not rely on the ventricular enhancement signal since regular pacing signals are of a shorter duration, lower energy, and are applied based on atrial needs.

Mower discloses the claimed invention except for the conveying a pacing signal having a shorter duration to a different chamber (claim 163) and in the absence of enhancement, conveying a signal with a lower energy (claim 167). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method using an atrial and ventricular pacemaker as taught by Mower, with conveying a pacing signal having a shorter duration to a the atrial chamber and in the absence of enhancement, conveying a signal with a lower energy since it was known in the art that atrial pacemakers use a pacing signal applied in the atrium having a shorter duration than 8 seconds to provide a pacing signal of low energy to pace the atrium and to apply with signal in the absence of the enhancement signals used in Mower to provide bradycardia support pacing to the atrium when needed.

Claim 174 is rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll or Mower or Freeman.

Kroll or Mower or Freeman discloses the claimed invention except for the sensing being a monophasic action potential signal. It would have been obvious to one having ordinary skill in

the art at the time the invention was made to modify the sensing and stimulation system as taught by Kroll or Mower or Freeman, with the sensing being a monophasic action potential signal since it was known in the art that sensing and stimulation systems sense a monophasic action potential signal to determine which portions of the heart are viable.

Claims 205 and 206 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kroll et al.

Kroll discloses the claim invention but does not disclose the pacing signal being a single pulse. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the cardiac pacing train signal as taught by Kroll with the pacing signal being a single pulse, because Applicant has not disclosed that the pacing signal being a single pulse provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the extended pacing train signal being greater than 8 ms as taught by Kroll, because the pulse train provides contraction of the heart to force hemodynamic output during times of need.

Therefore, it would have been an obvious matter of design choice to modify Kroll to obtain the invention as specified in the claim(s).

Allowable Subject Matter

Claims 6, 7, 55, and 56 are allowed.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by amendment. The 112 first paragraph

rejection has been withdrawn since the applicant argued that the first portion of the greater than 8 ms pulse is what initiates the action potential propagation. Although during the first 1-2 ms of the greater than 8 ms pulse there is no action potential, the first 1-2 ms is what "initiates" or starts the action potential. This is similar to Mowers alternative embodiment subthreshold first phase pulse. In addition, Mower says the subthreshold first phase is an alternative embodiment and uses "and/or" when describing the first phase. If the first phase is not subthreshold, it is therefore a stimulation/above threshold pulse. In addition, the art of Kroll still applies to the claims since the pulses are delivered every 500 ms, providing for 2-3 pulses at a heart rate of 60 bpm. It is noted that the limits/range of "a single heartbeat" has not been defined and that a normal resting heart rate is approximately 60 bpm. Finally, a new 112 first paragraph rejection has been made since "within a single heartbeat" was not in the original specification. Although the applicant argues that it would have been obvious to one having ordinary skill in the art to understand that the pulse was "within a single heartbeat", this is not persuasive since the prior art shows alternative embodiments which are not within a single heartbeat. Since alternatives exist for when the duration of the pulse occurs, the applicant can not therefore rely on "within a single heartbeat". Although, it is noted that the applicant does has support for delivering the pulse so that it terminates during the refractory period (page 11 of the specification).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

George R Evanisko
Primary Examiner
Art Unit 3762
6/26/6

GRE
June 26, 2006